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The value of tokenizing clinical development data for real-world evidence–based use cases

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There is an ever-present need to accelerate clinical development to ensure that therapies and devices can reach patients as quickly as possible. Real-word data (RWD) offers the opportunity to focus on the needs of patients while reducing unnecessary spend if used correctly. However, there are existing challenges to overcome to realize the benefit.

Where we are today

The 21st Century Cures Act includes a mandate that regulators consider using RWD/RWE to inform regulatory decisions, and similar requirements are becoming more commonplace globally. Given the diversity and availability of RWD, there are increased expectations from regulators that clinical research will leverage these rich data sources to:

- Reduce overall trial costs through optimized trial designs (i.e. trial feasibility, endpoint selection) and accelerating the time to achieve trial outcomes (i.e. site feasibility, cohort modeling)
- Support approvals and other regulatory submissions (i.e. external/synthetic control arms, label expansions)
- Provide evidence of improved health outcomes and/or reduced health spend while therapies are in development (pre-commercialization) in support of value-based care and contracts
- Streamline comparative effectiveness research
- Evaluate social determinants of health and the impact on trial participants
- Improve understanding of responders/non-responders
- Optimize long-term follow-up activities, such as drug safety monitoring, maternal health studies, post-approval confirmatory studies, and post-market safety/efficacy studies

One of the main challenges to making these lofty goals a reality is safely and compliantly co-mingling RWD and clinical development data. Some real-world data sets with identifiable information — in particular when patients have given consent — can be integrated by using a patient's name, date of birth, gender, or other information. However, to get a true holistic view of the patient, linking deidentified data sets becomes critical. Using and representing some data is hindered because RWD is not collected with research as its primary purpose. Tokenization of the clinical development data is an efficient way to enable the linkage of clinical development data with real-world data.

Moving Forward

To realize the full potential of RWD in clinical development, it is important to understand that using RWD does not need to be an "either/or" decision. RWD should be assessed with the lens of "fit for this purpose" versus "fit for any purpose." The clinical development strategy should be developed including RWD in structured and meaningful ways, and it should be tied to clear and measurable use cases.

In terms of deriving value from real-world data, the most prominent use cases in the industry right now do not require tokenization of the clinical research data to deliver the value. However, given that accessing and linking RWD are the greatest challenges to the full realization of the RWD promise, innovative methods for bringing disparate data sources together, including tokenization, provide an effective way to address the challenges. The return on investment from tokenization of clinical trial data is a key part of defining an RWD strategy.
Tokenization of clinical trial data delivers a meaningful return on investment in a few ways. By tokenizing clinical trial data and linking it with Health Record and Claims data, companies would be better able to:

- Confirm trial eligibility and reduce enrollment costs
- Evaluate long-term effectiveness and safety, including mortality and maternal-infant linkage
- Measure impact of therapies on healthcare utilization and quantify therapeutic benefit

Considerations for tokenizing RWD in clinical development

An aspect of the tokenization concept that can be easily overlooked is execution. You must establish, from the beginning, a straightforward method to collect and securely store the data required to create a robust token. Tightly integrating eConsent technology with the electronic data capture (EDC) system offers an excellent solution for this challenge, because eConsent provides a method for capturing the key patient identifiable information (PII) to establish a token (along with the benefits of helping facilitate patient consent, assent, and re-consent). Associating PII with EDC case report form datapoints during the tokenization process builds the strength of the token for downstream linking. Having a unified system that offers segregated/encrypted storage of PII and the ability to securely connect the deidentified clinical data is ideal for facilitating tokenization effort.

Success in tokenizing RWD requires a plan:

- Establish the tokenization inputs during protocol development.
- Select systems that offer a secure method for unifying PII with de-identified clinical data needed for a robust token.
- Offer straightforward tools for both study participants and their representatives to manage consent.
- Incorporate the intended use of the data into

Tokenizing a dataset is not difficult and can be done at strategic times during study conduct or as needed for analysis purposes. With a sound approach to collecting and managing the key inputs, datasets can be tokenized via various methods and vendors to further the downstream linking prospects. However, if you do not have a reliable plan to collect the data from the outset, then the overall downstream value of your dataset will suffer.

Given the increasing need to accelerate clinical development and reduce unnecessary spend — and the potential that RWD provides to accelerate those outcomes — developing an RWD strategy that is inclusive of tokenization can be a game changer. The greatest challenges with RWD are access and linkage, and even though linkage between real-world datasets is possible without tokenization, the return on investment of a well-planned and applied tokenization strategy can accelerate use case adoption of RWD in clinical development.

Explore how Zelta supports trial design to help accelerate clinical development.

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